



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/480,472	06/06/95	MCDONOUGH	S 213/066

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18M2/0318

EXAMINER

TRAN, P

ART UNIT

PAPER NUMBER

1807

DATE MAILED: 03/18/97

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/480,472**

Applicant(s)  
**McALLISTER ET AL.**

Examiner  
**PAUL B. TRAN**

Group Art Unit  
**1807**



☒ Responsive to communication(s) filed on Jun 28, 1996

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ONE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 24-42, 48-51, and 54-99 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 24-42, 48-51, and 54-99 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**Part III DETAILED ACTION**

1. The examiner acknowledges the receipt of Applicant's Preliminary Amendment filed June 28, 1996, which adds new claims 57-99. In view of this amendment the following restriction/election of species is required.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 24-42, 48-51 and 54-56, drawn to promoter-primer and kit and composition comprising thereof and/or RNA- and DNA polymerase, classified in Class 435, subclass 91.1.

Group II. Claims 39-42, 57-99, drawn to a probe or oligonucleotide targeted to *M. tuberculosis*, classified in Class 536, subclass 24.32.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct and independent from each other. The subject matter of Invention I is drawn to a promoter-primer and primer, which are modified or unmodified at their 3' ends. These modified promoter-primer or primer are distinct and independent from the primer or probe drawn in Invention II. The oligonucleotides which are targeted to *M. tuberculosis* in Invention II do not have this modification as drawn in Invention I. Therefore, the two inventions are distinct and independent from each other.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, and vice versa, restriction for examination purposes as indicated is proper.

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5. Should Applicant elect Group II, an election of species is also required as follows:

Claims 39-42 and 57-99 are generic to a plurality of disclosed patentably distinct species comprising oligonucleotides whose sequences are directed to a number of target regions set forth in SEQ ID NOS. 2-5, 7-10, 22 and 23. These sequences are patentably distinct species because they are located in different regions of the *M. tuberculosis* genome, and thus different in nucleotide sequence. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, i.e. a SEQ ID NO., even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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8. Any inquiry concerning this communication or those earlier from the examiner should be directed to Paul B. Tran, Ph.D., whose telephone number is (703) 308-4040.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose phone number is (703) 308-0196.

Paper related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Paul B. Tran, Ph.D.   
Art Unit 1807  
3/14/97

  
**PAUL TRAN**  
**PATENT EXAMINER**  
**GROUP 1800**